IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AbbVie Inc. *et al.*, Plaintiffs/Counterclaim-Defendants, v. Boehringer Ingelheim International GmbH *et al.*, Defendants/Counterclaim-Plaintiffs.	C.A. No. 17-1065-MSG-RL [redacted] REDACTED VERSION

BOEHRINGER'S REPLY IN SUPPORT OF ITS MOTION TO COMPEL ABBVIE TO RUN ADDITIONAL SEARCH TERMS

The crux of AbbVie's opposition is that it should not be required to run five additional electronic search terms because (i) there is no guarantee that these searches will only and exclusively return relevant, non-duplicative documents, and (ii) running the searches is burdensome because it will require AbbVie to review more documents. Neither argument withstands scrutiny. Under Paragraph 5(b) of the Default Standard, Boehringer is permitted to propose "10 additional terms" to "locate ***potentially responsive*** ESI." (Emphasis added.) The proposed terms do just that, specifically connecting the subject matter of the asserted patents with adalimumab in a "[f]ocused" way. This is proven by the fact that they return relevant documents beyond those searched thus far by AbbVie. In an effort to meet AbbVie's continuing and shifting complaints about the volume of those searches, Boehringer has worked to narrow its proposed terms to avoid false positives and locate primarily responsive documents.[1] Given the resources available to AbbVie and the importance of this litigation, there is no undue burden in

[1] For example, AbbVie alleged that "partic*" and "poten*" contributed to the burden on May 16. (D.I. 94 (2nd Ex. G at 1-2 [May 17, 2018 email]).) Boehringer listened to this concern and modified "partic*" to "particulate*" and removed "poten*", only for AbbVie to then say that focusing down these terms and adding other narrowing criteria amounted to only "token reduction[s]." (D.I. 94 at 2.)

collecting and reviewing documents that should already have been produced. The additional limitations AbbVie seeks to impose on the search terms are unjustified.

First, the Court should reject AbbVie's attempt to exclude relevant custodians. AbbVie does not dispute that Paragraph 5(b) of the Default Standard specifies applying search terms to "emails and other ESI ***maintained by the custodians identified in accordance with Paragraph 3(a).***" (emphasis added). That rule refutes AbbVie's opposition. AbbVie's proposed exclusions are also especially improper because, as noted in Boehringer's Motion, AbbVie identified custodians as knowledgeable about (and thus likely to have information relevant to), *inter alia*, the manufacturing processes, analytical techniques, and validation processes for Humira®, which are implicated by the search terms. (D.I. 75 at 2-3.) Similarly, because AbbVie is wrong when it asserts that stability-related terms are only relevant to the asserted formulation patent,[2] AbbVie cannot categorically exclude non-formulation custodians from portions of search term 2 as it seeks to do.

Second, AbbVie should be required to run Boehringer's compromise "G terms" from search term 6. AbbVie does not dispute that search term 6 is made up of non-standard, technical terms (*e.g.*, "*FG0*" and "*G1F*") related to the subject matter of the '143 patent. Search term 6 is thus not only focused but it very likely will return ***only*** documents relating to the various oligosaccharide forms at issue in the '143 patent (not "common" terms sharing these letters).[3] AbbVie's statement that this search will yield approximately 35,000 documents not only fails to

[2] *See, e.g.*, Non-formulation U.S. Patent No. 9,018,361 at 3:4-12 ("***In certain embodiments, the present method*** . . . involves the use of hydrophobic interactive chromatography . . . . It is possible that the antibodies of interest ***have formed aggregates*** during the isolation/purification process. This hydrophobic chromatographic step facilitates ***the elimination of these aggregations***.") (emphasis added).

[3] AbbVie is wrong that because these key terms (*e.g.*, "FG0") also appear in scientific articles production is unwarranted. (D.I. 94 at 5-6 n. 3; D.I. 75, Ex. H.) To the contrary, the cited article demonstrates that the search term is one way the scientific community refers to the oligosaccharide forms.

justify foreclosing this important discovery, but confirms its importance. AbbVie excluded all these relevant, non-duplicative documents from its production.

Third, AbbVie should not be permitted to use the connector "w/20" rather than "w/200" for search terms 2-3 and 6-8. The proposed search terms employ technical terms ***related to the subject matter of AbbVie's asserted patents*** in conjunction with a connector ("w/200") that logically and reasonably associates those terms with adalimumab and its project codes; they are not simply "common scientific terms" and the w/200 is not arbitrary. For example, "shake flask" (in term 6) is relevant to, and cited in the specification of, U.S. Patent No. 9,255,143 patent as being part of the cell culture process used to create the claimed compositions (at 23:6-10); "sodium chloride" and "pH" (in term 3) relate to formulation components and characteristics (the subject of U.S. Patent No. 9,272,041, *see, e.g.*, 7:1-5); and "pH" relates to characteristics of the claimed adalimumab manufacturing process (U.S. Patent No. 9,090,867, claim 1). The connector range reflects the fact that not all responsive documents will have the pertinent search terms within 20 words of each other. (*See* D.I. 75 at 4 & Ex. G.)[4] Finally, the Default Standard (¶5(b)) requires only that search terms be "[f]ocused" to return "potentially responsive ESI," not that they guarantee the identification of only responsive documents, and these terms are squarely within the Default Standard protocol.[5]

For the reasons set forth above and in its Motion, Boehringer respectfully requests the Court order AbbVie to run the requested search terms.[6]

[4]AbbVie is incorrect that because another search term it used captured one such document, the proposed search terms unnecessary. (D.I. 94 at 5.) Of course Boehringer does not have access to AbbVie's unproduced documents, but the fact that new documents are being returned by the additional terms shows that those terms are not merely duplicative of existing terms and will return non-duplicative documents.

[5] If AbbVie needs a modest adjustment to the document production schedule to produce documents that are long overdue, and such adjustment will not impact the case schedule, AbbVie should have raised that with Boehringer. It is not an excuse to avoid production.

[6] A revised proposed order, consistent with the parties' briefing, is attached hereto.

Dated: May 23, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, James D. Taylor, Jr., Esquire, hereby certify that on the 23rd day of May, 2018, a copy of Defendants' Boehringer Ingelheim International GmbH, Boehringer Ingelheim Pharmaceuticals, Inc., and Boehringer Ingelheim Fremont, Inc.'s ***Reply in Support of its Motion to Compel AbbVie to Run Additional Search Terms*** was caused to be served via e-mail on the following counsel of record:

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FOR THE DISTRICT OF DELAWARE

AbbVie Inc. and AbbVie Biotechnology Ltd, Plaintiffs/Counterclaim-Defendants, v. Boehringer Ingelheim International GmbH, Boehringer Ingelheim Fremont, Inc., and Boehringer Ingelheim Pharmaceuticals, Inc. Defendants/Counterclaim-Plaintiffs.	C.A. No. 17-1065-MSG-RL

ORDER

AND NOW, this _____ day of May, 2018, upon consideration of Boehringer's Motion to Compel AbbVie to Run Additional Search Terms Pursuant to Paragraph 5(b) of the Default Standard, the Plaintiffs' response, and Boehringer's reply thereto, it is hereby

ORDERED

that the Motion is **GRANTED**. Plaintiffs shall run the below additional search terms 2, 3, 6, and 7 against all custodial and noncustodial data sources other than those involved solely in clinical research.

> 2. (*stable OR *stabil* OR (freez* AND thaw*) OR ultraviolet OR UV OR visc* OR aggregat* OR precipitat* OR particulate* OR calor* OR electro* OR shak* OR ((25 OR 30 OR 40 OR 2 OR 8) w/5 (degree*)) OR (25° OR 30° OR 40° OR 2° OR 8°) OR (shelf w/2 life) OR (mass w/5 spectr*) OR "mass spec" OR (size w/5 exclu*) OR SEC OR GPC OR GFC OR "gel filtration" OR deamid* OR denat* OR degrad* OR clip*) W/200 (Humira OR Humira* OR D2E7 OR adalimumab OR LU200134 OR "LU 200134" OR 125057)

3. (NaCl OR sodium chloride OR PS80 OR PS20 OR “PS 80” OR “PS 20” OR pH) W/200 (Humira OR Humira* OR D2E7 OR adalimumab OR LU200134 OR "LU 200134" OR 125057)

6. (*fucosyl* OR oligosaccharide* OR “N-linked” OR glycan* OR *galactosyl* OR *NGA2F* OR *NA1F* OR *NA2F* OR *FG0* OR *G0F* OR *FG1* OR *G1F* OR *FG2* OR *G2F* OR “shake flask*”) W/200 (Humira OR Humira* OR D2E7 OR adalimumab OR LU200134 OR "LU 200134" OR 125057)

7. (hydrolysate* OR glutamine OR rice OR cotton OR seed OR pea OR corn OR potato OR yeast* OR soy* OR wheat* OR phyto* OR peptone OR supplement* OR enrich*) W/200 (Humira OR Humira* OR D2E7 OR adalimumab OR LU200134 OR "LU 200134" OR 125057)

Plaintiffs shall further run the below additional search term 8 on all custodial and noncustodial data sources.

8. (PK or pharmaco* OR PK* OR “PD”) W/200 (Humira OR Humira* OR D2E7 OR adalimumab OR LU200134 OR "LU 200134" OR 125057)

BY THE COURT:

_____

Honorable Richard A. Lloret
United Stated Magistrate Judge